DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 25, 2014

Philips Medizin Systeme Böblingen GmbH
Michael Asmalsky
Regulatory Affairs Engineer
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Germany

Re: K140535
Trade/Device Name: Philips Avalon Fetal/Maternal Monitors FM20 (M2702A), FM30 (M2703A), FM40 (M2704A) and FM50 (M2705A)
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: Class II
Product Codes: HGM, HGL, HFM, JOM, HFN, DXN, DSK, DSJ, DQA, DRG, DSF, DRT, DRQ, DSA, FLL
Dated: October 23, 2014
Received: October 27, 2014

Dear Michael Asmalsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140535

Device Name
Philips Avalon FM20(M2702A), FM30(M2703A), FM40(M2704A) and FM50(M2705A).

Indications for Use *(Describe)*

Avalon Fetal/Maternal Monitor FM20:
Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters uterine activity, heart rate, oxygen saturation, noninvasive blood pressure, pulse rate and temperature of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms, in antepartum testing areas, in private households and during transports in healthcare facilities.

Avalon Fetal/Maternal Monitor FM30:
Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters uterine activity, heart rate, electrocardiography (ECG), oxygen saturation, noninvasive blood pressure, pulse rate and temperature of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms, in antepartum testing areas, in private households and during transports in healthcare facilities.

Avalon Fetal/Maternal Monitor FM40:
Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters uterine activity, heart rate, oxygen saturation, noninvasive blood pressure, pulse rate and temperature of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms and in antepartum testing areas.

Avalon Fetal/Maternal Monitor FM50:
Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters uterine activity, heart rate, electrocardiography (ECG), oxygen saturation, noninvasive blood pressure, pulse rate and temperature of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms and in antepartum testing areas.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) Summary

Avalon Fetal/Maternal Monitor FM20/30, FM40/50, Release J.3

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

Submitters Name:

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Date of Summary:

This summary was prepared on October 22nd, 2014.

Trade Name of the Device:

Philips Fetal/Maternal Monitor
Avalon FM20 (M2702A), FM30 (M2703A), FM40 (M2704A), FM50 (M2705A) with software revision J.30 ("J.3" release)

Common Name:

Perinatal monitor and accessories

Classification:

Device Panel	Classification	ProCode	Description
Obstetrical and Gynecological Monitoring Devices	§884.2740, II	HGM	Perinatal monitoring system and accessories
Obstetrical and Gynecological Monitoring Devices	§884.2960, II	HGL	Obstetric ultrasonic transducer and accessories
Obstetrical and Gynecological Monitoring Devices	§884.2720, II	HFM	External uterine contraction monitor and accessories
Cardiovascular Devices	§870.2780, II	JOM	Hydraulic, pneumatic, or photoelectric plethysmographs
Obstetrical and Gynecological Monitoring Devices	§884.2700, II	HFN	Intrauterine pressure monitor and accessories
Cardiovascular Devices	§870.1130, II	DXN	System, Measurement, Blood-Pressure, Non-Invasive
Cardiovascular Devices	§870.1110, II	DSK	Computer, Blood Pressure
Cardiovascular Devices	§870.1100, II	DSJ	Alarm, Blood Pressure
Cardiovascular Devices	§870.2700, II	DQA	Oximeter

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Device Panel	Classification	ProCode	Description
Cardiovascular Devices	§870.2910, II	DRG	Radiofrequency physiological signal transmitter and receiver
Cardiovascular Devices	§870.2810, I	DSF	Recorder, Paper Chart
Cardiovascular Devices	§870.2300, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm)
Cardiovascular Devices	§870.2060, II	DRQ	Amplifier and Signal Conditioner, Transducer Signal
Cardiovascular Devices	§870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient Connector
General Hospital and Personal Use	§880.2910, II	FLL	Thermometer, Electronic, Clinical

Predicate Devices:
Philips Avalon Fetal/Maternal Monitors FM20, FM30, FM40 and FM50 (most recent clearance K111083, primary predicate device) and

Philips M2720A Avalon CTS Cordless Fetal Transducer System (most recent clearance K023931).

Reference Devices:
Philips IntelliVue Patient Monitors MP5 and MP5SC, (most recent clearance K131829)

Philips IntelliVue CL SpO2 Pod, Philips IntelliVue CL NBP Pod and Philips IntelliVue Patient Monitor MP5, MP5T and MP5SC, (most recent clearance K131913) and

Philips IntelliVue Patient Monitor MP 70, (most recent clearance K122439).

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Device Description:

The legally marketed Philips Avalon fetal/maternal monitors FM20, FM30, FM40, and FM50 offer monitoring of fetal and maternal heart rates, uterine activity, maternal electrocardiography (ECG) wave, maternal noninvasive blood pressure (NIBP), oxygen saturation (SpO_2) with pulse rate and temperature, during antepartum testing and labor and delivery.

The **Avalon Fetal/Maternal Monitor FM20** provides the following external measurement parameters:

- Up to three Fetal Heart Rates (FHR) via Ultrasound (US)
- Fetal Movement Profile
- Uterine activity via external Toco
- Maternal pulse rate
- Maternal Heart Rate via maternal ECG
- Noninvasive blood pressure (NBP)
- Maternal temperature
- Pulse oximetry (maternal SpO_2)

The **Avalon Fetal/Maternal Monitor FM30** shares all the features and capabilities of the Avalon FM20. In addition, the Avalon FM30 provides the following external and internal measurement parameters:

- One Fetal Heart Rate and one fetal DECG wave via direct ECG (DECG) *)
- Uterine activity via intrauterine pressure (IUP)
- Maternal ECG (MECG) wave

*) Note: maximum three fetal heart rates can be monitored.

The **Avalon Fetal/Maternal Monitor FM40** provides the following external measurement parameters:

- Up to three Fetal Heart Rates (FHR) via Ultrasound (US)
- Fetal Movement Profile
- Uterine activity via external Toco
- Maternal Pulse Rate
- Maternal Heart Rate via maternal ECG
- Noninvasive blood pressure (NBP)
- Maternal temperature
- Pulse oximetry (maternal SpO_2)

The **Avalon Fetal/Maternal Monitor FM50** shares all the features and capabilities of the Avalon FM40. In addition, the Avalon FM50 provides the following external and internal measurement parameters:

- One Fetal Heart Rate and one fetal DECG wave via direct ECG (DECG) *)
- Uterine activity via intrauterine pressure (IUP)
- Maternal ECG (MECG) wave

*) Note: maximum three fetal heart rates can be monitored.

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Device Modifications

The device modifications of the subject Philips Avalon fetal/maternal monitors FM20, FM30, FM40, and FM50 include the following changes:

- Provide an interface to optionally measure the noninvasive maternal temperature using the Philips tympanic temperature module as cleared with the Philips IntelliVue MP5 patient monitors with K131829.

- Modification to the current legally marketed Avalon fetal/maternal monitor transducers so that they support cableless measuring of fetal and maternal parameters, including measuring fetal/maternal parameters in a bath or shower, now also when using the cableless Avalon CL transducers Toco+MP, Ultrasound and ECG/IUP.

- Provide an interface to optionally measure noninvasive maternal blood pressure and maternal oxygen saturation with pulse rate using the cableless IntelliVue CL SpO2 Pod and NBP Pod as cleared with the Philips IntelliVue MP5, MP5T and MP5SC patient monitors with K131913.

- The option to equip a Philips Avalon fetal/maternal monitor with a flexible nurse call relay interface and a USB interface as cleared with the Philips IntelliVue MP70 patient monitor with K122439.

- To support these purposes the software of the Avalon fetal/maternal monitors has been slightly modified. With this modification additional software enhancements, such as the acoustical annunciation of the technical heart/pulse-rate coincidence alarm (INOP) and annotation of the source of displayed waves have been added. The modified common software revision of the Avalon fetal/maternal monitors is Rev.J.30.

All other measurement parameters that contain signal acquisition and physiological algorithms remain unchanged in this Premarket Notification.

Indications for Use:

Avalon Fetal/Maternal Monitor FM20:
Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters uterine activity, heart rate, oxygen saturation, noninvasive blood pressure, pulse rate and temperature of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms, in antepartum testing areas, in private households and during transports in healthcare facilities.

Avalon Fetal/Maternal Monitor FM30:
Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters uterine activity, heart rate, electrocardiography (ECG), oxygen saturation, noninvasive blood pressure, pulse rate and temperature of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms, in antepartum testing areas, in private households and during transports in healthcare facilities.

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Avalon Fetal/Maternal Monitor FM40:
Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters uterine activity, heart rate, oxygen saturation, noninvasive blood pressure, pulse rate and temperature of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms and in antepartum testing areas.

Avalon Fetal/Maternal Monitor FM50:
Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters uterine activity, heart rate, electrocardiography (ECG), oxygen saturation, noninvasive blood pressure, pulse rate and temperature of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms and in antepartum testing areas.

Technological Characteristics:

The fundamental scientific technology employed in the operation of the Philips Avalon fetal/maternal monitors FM20, FM30, FM40 and FM50 has not changed from that of the predicate devices as a result of the modification.

Non-clinical Testing:

Verification and validation activities established the performance, functionality, and reliability characteristics of the modified devices with respect to the predicates. Testing involved biocompatibility testing, testing from the hazard analysis, software, performance and regression verification tests, EMC and safety testing and bench testing.

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Pass/Fail criteria were based on the specifications cleared for the predicate devices. The test results are passed and showed substantial equivalence. Bench testing included the use of previously recorded patient raw signals and traces. The verification and validation tests included:

- Biocompatibility testing for the modified materials was conducted as follows:
  - Cytotoxicity according to EN IS0 10993-5
  - Irritation according to EN IS0 10993-10
  - Delayed Type Hypersensitivity according to EN IS0 10993-10
  - Chemical characterization according to EN IS0 10993-18

- Testing of new or impacted hazards as indicated by the extracts of the risk management summary as described in section 16.7.1.

- Software performance and regression verification and validation not covered by the risk and hazard analysis as described in section 16.7.2

- Performance and regression verification testing of the wireless functionality, including the applicable sections of the Guidance for Industry and Food and Drug Administration Staff for Radio Frequency Wireless Technology in Medical Devices issued on August 14, 2013, as described in section 16.7.3

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- Verification according to the applicable EMC, safety, and performance standards was conducted as described below:

Standard	Type
AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Basic safety and essential performance)	Basic safety and essential performance
IEC 60601-1-2:2007	Electromagnetic Compatibility
IEC 60601-1-6:2010 (incorporating AAMI ANSI IEC 62366:2007)	Usability
IEC 60601-1-8:2006	Alarms
IEC 60601-2-27:2011	ECG
IEC 80601-2-30:2009	NBP
IEC 60601-2-37:2007	Ultrasound
ISO 80601-2-56	Clinical thermometer for body temperature
ISO 80601-2-61:2011	SpO_2 Monitoring
IEC 62304:2006	Software life cycle processes
AAMI ANSI ISO 10993-1:2009	Biocompatibility

- Bench testing as described in section 18.

Clinical Testing:

No clinical studies were necessary to demonstrate substantial equivalence.

Conclusion:

The non-clinical verification and validation results demonstrate that the Avalon fetal/maternal monitors with software J.30 are as safe, as effective, and perform as well or better as the predicate devices with software G.02.xx. The modified devices do not introduce new questions concerning the safety or effectiveness and are, therefore, substantially equivalent to the predicate devices.